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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,229	09/26/2003	Vinod Sharma	P-11083.00	2880

27581 7590 04/20/2006

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EXAMINER	
KRAMER, NICOLE R	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,229	SHARMA, VINOD	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2004/0106956 ("Sharma et al.").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Sharma et al. discloses a method of delivering ATP regimens comprising (a) upon detection of a tachycardia episode (see, for example, step 410 of Fig. 4 in which tachycardia episode is detected), delivering an exploratory ATP sequence of pacing pulses to the heart chamber to elicit a paced depolarization of the heart chamber upon

delivery of at least the last delivered ATP pulse (see, for example, step 412 of Fig. 4 in which an ATP regimen is delivered); (b) measuring an exploratory return cycle length (RCL) from the last delivered exploratory ATP sequence pacing pulse to the next detected intrinsic depolarization (see step 418 of Fig. 4 in which the IMD computes the Return Cycle Length, described in the specification as the time elapsed since the last delivered ATP pulse and sensing of a subsequently received pulse at paragraph 0055); (c) formulating an ATP regimen having ATP parameters defined as a function of the measured exploratory RCL (based on the calculated RCL, the IMD discriminates between VT and SVT as described at paragraphs 0055 - 0056. The therapy to be delivered differs depending upon whether the IMD determines that the episode is a VT or a SVT, and thus the IMD formulates an ATP regimen having ATP parameters as a function of the measured RCL); and (d) delivering the ATP regimen to the heart chamber.

With respect to claim 19, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in Sharma et al. (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments).

3. Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,167,308 ("DeGroot").

DeGroot discloses a method of delivering ATP regimens comprising (a) upon detection of a tachycardia episode, delivering an exploratory ATP sequence of pacing pulses to the heart chamber to elicit a paced depolarization of the heart chamber upon delivery of at least the last delivered ATP pulse (see, for example, col. 2, lines 46-61 in which two series of short series of ATP pulses are delivered); (b) measuring an exploratory return cycle length (RCL) from the last delivered exploratory ATP sequence pacing pulse to the next detected intrinsic depolarization (after delivery of the second series of pulses, the IMD measures the return cycle T4 as described at col. 2, lines 61-63); (c) formulating an ATP regimen having ATP parameters defined as a function of the measured exploratory RCL (depending on a comparison between return cycle T4 and a previously measured return cycle T3, the device either continues delivery of pacing pulses separated by intervals T2 or switches to different therapy as described at col. 2, lines 63-66. Since the therapy to be delivered differs depending on measured return cycle T4, the IMD formulates an ATP regimen having ATP parameters as a function of the measured RCL); and (d) delivering the ATP regimen to the heart chamber.

With respect to claim 19, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in DeGroot (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for

pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2-18 and 20-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,167,308 ("DeGroot") in view of U.S. Patent No. 6,400,986 ("Sun et al.").

As described above, DeGroot teaches formulating an ATP regimen having ATP parameters defined as a function of a measured exploratory RCL (depending on a comparison between return cycle T4 and a previously measured return cycle T3, the device either continues delivery of pacing pulses separated by intervals T2 or switches to different therapy as described at col. 2, lines 63-66). In the method disclosed in DeGroot, if the return cycle T4 increases in comparison to return cycle T3, the IMD continues to deliver pacing pulses at the same pacing interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia. However, if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen or a cardioversion pulse (see, for example, col. 5, line 43 - col. 6, line 30).

DeGroot fails to that the next available therapy may be selected based upon previously successful ATP regimens that successfully terminated a tachycardia when similar return cycles were calculated. Sun et al. teaches an IMD with ATP capability that is programmed to deliver ATP therapy upon detection of a tachycardia by employing a pacing regimen selected from a library, or database, of previously successful or unsuccessful pacing protocols (see col. 2, lines 20-53). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method and device of DeGroot to select the next available therapy based upon previously successful ATP regimens that successfully terminated a tachycardia as taught by Sun et al. in order to terminate the tachycardia as quickly and efficiently as possible by selecting a pacing regimen that successfully terminated a tachycardia when similar return cycles were calculated.

With respect to claims 3, 21, 25, and 36, Sun et al. teaches the use of success/failure counters associated with each pacing protocol contained in the library. After each attempt of ATP therapy using a particular protocol, the relevant counter is incremented to indicate the success or failure of the protocol in terminating the arrhythmia (see, for example, col. 2, lines 54-59).

With respect to claims 4-7, 15-16, 22, 26-29, and 37-38, DeGroot detects whether a tachycardia is occurring (see, for example, step 200 of Fig. 4a) and also detects whether the tachycardia terminates in response to delivered ATP pacing therapy (see col. 5, lines 55-60). Detection of whether the tachycardia has terminated includes determining a post-ATP rate (see col. 5, lines 55-60). Although not explicitly

stated, DeGroot utilizes a pre-ATP rate to detect whether a tachycardia episode is occurring (in the alternative, Applicant admits that it is known for a ICD to employ tachycardia classification algorithms that utilize detected heart rates in order to detect a tachycardia; see Applicant's specification at page 2. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the IMD of DeGroot to detect the pre-ATP rate in order to detect a tachycardia as is well known in the art in order to accurately detect a tachycardia condition). If the post-tachycardia rate is still determined to be a tachycardia but is different from the pre-ATP rate (i.e., if the tachycardia rate is decelerating, the same, or accelerating), it would have been obvious to one having ordinary skill at the time of applicant's invention to modify the combined IMD of DeGroot and Sun et al. to record in the result table/database whether the unsuccessful pacing regimen resulted in accelerating or non-accelerating tachycardia rate in order to provide a physician with more information regarding the effect of a particular pacing regimen on the patient's tachycardia condition. Further, if the tachycardia condition is deemed to be accelerating, it is known in the art that a cardioversion or defibrillation may be required (see, for example, U.S. Patent No. 4,998,974 to Aker).

With respect to claims 8-10, 18, and 30-32, DeGroot discloses that if the return cycle T4 increases in comparison to return cycle T3, the IMD increases the number of ATP pulses delivered (the IMD continues to deliver pacing pulses at the same pacing interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia). In addition, DeGroot discloses that

if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen or a cardioversion pulse (see, for example, col. 5, line 43 - col. 6, line 30). The new pacing regimen may include reducing the inter-pulse pacing interval (see col. 6, lines 20-25).

With respect to claims 11-12, 14, 17, 23, and 34, Sun et al. teaches that the information contained in the success/failure counters may be used to calculate a success/failure ratio (see, for example col. 2, lines 59-63 and col. 6, lines 1-37). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method and device of DeGroot to select a therapy having the highest stored efficacy as taught by Sun et al. in order to terminate the tachycardia as quickly and efficiently as possible.

With respect to claims 19-38, Examiner notes that applicant has invoked 112, 6th paragraph for various claim elements. Examiner considers the means disclosed in DeGroot and or Sun et al. (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments) to be equivalent to the means disclosed in the specification of the current application (i.e., electrodes for pacing and sensing cardiac activity and a microprocessor based controller for delivering and formulating ATP pacing regiments).

Response to Arguments

6. With respect to the rejections based on Sharma et al. and DeGroot, Applicant's arguments filed 4/12/06 have been fully considered but they are not persuasive.

7. More specifically, Applicant first argues that Sharma et al. fails to disclose "formulating an ATP regimen having ATP parameters defined as a function of the measured exploratory RCL." Applicant argues that Sharma does not discuss modifying the ATP regimen applied when the episode was detected. However, the claim recitation "formulating an ATP regimen" does not necessarily require that the scheduled ATP therapy by modified. While Examiner considers the broadest interpretation of the term "formulate" to include modifying or creating a new ATP regimen (i.e., invent or put together a new ATP regimen), Examiner also considers "formulate" to encompass the expression or application of an ATP regimen (i.e., determine whether to apply a particular ATP regimen), even if the ATP regimen is not new or modified. Since Sharma discloses that the therapy to be delivered differs depending upon whether the IMD determines that the episode is a VT or a SVT (for example, if the episode is determined to be a VT, scheduled therapy is delivered as illustrated in step 422 of Fig. 4, but if the episode is determined to be an SVT, therapy is withheld as illustrated in step 424 of Fig. 4), Examiner considers the IMD to "formulate an ATP regimen as a function of the measured RCL."

8. Similarly, Applicant argues that DeGroot fails to disclose "formulating an ATP regimen having ATP parameters defined as a function of the measured exploratory RCL." Applicant argues that DeGroot discloses that after the RCL is measured, the applied ATP regimen has predetermined or predefined parameters and thus DeGroot does not teach formulating an ATP regimen. However, while Examiner considers the

broadest interpretation of the term "formulate" to include modifying or creating an ATP regimen (i.e., invent or put together a new ATP regimen), Examiner also considers "formulate" to encompass the expression or application of an ATP regimen (i.e., select or determine which ATP regimen to apply), even if the ATP regimen has predetermined or predefined parameters. In the method disclosed in DeGroot, if the return cycle T4 increases in comparison to return cycle T3, the IMD continues to deliver pacing pulses at the same pacing interval because the increasing return cycle is an indicator that the current pacing interval will successfully terminate the tachycardia. However, if the return cycle T4 does not increase in comparison to return cycle T3, the IMD schedules the next available therapy, which may be a new pacing regimen (see, for example, col. 5, line 43 - col. 6, line 30). Since the IMD of DeGroot selects which ATP regimen to apply based on the measured RCL, Examiner considers the IMD to "formulate an ATP regimen as a function of the measured RCL."

9. Applicant's arguments, see page 20, filed 4/12/06, with respect to the rejection of claims 1 and 19 based on Sowton et al. have been fully considered and are persuasive. The rejection of claims 1 and 19 has been withdrawn because Sowton et al. teaches measuring subsequent RR intervals rather than measuring the RCL from the last delivered ATP pacing pulse to the next detected intrinsic depolarization (see col. 1, lines 51-61).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
4/13/06

George Manuel
Primary Examiner